Multitak SS
FROM BONUTTI RESEARCH

MAY - 8 2001

K010479

Bonutti Research, Inc.
Multitak™ Conical Tip Soft Tissue Suture Anchor
510(k) Premarket Notification

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

Contact Person: Patrick Balsmann, MS, RAC,
Manager, QA & Regulatory/Clinical Affairs
Bonutti Research, Inc.,
P.O. Box 1367, Effingham, Illinois 62401
Phone: 217.342.3412, ext. 321

Date Prepared: February 19, 2001

Proprietary Name: Multitak™ Conical Tip Soft Tissue Suture Anchor

Common Name: Soft Tissue Anchor

Classification Name: 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.

Device Description: The Multitak™ conical tip soft tissue suture anchors are cylindrical suture anchors with a conical tip on one end. The anchors are manufactured from a titanium alloy and have two transverse suture holes. The soft tissue anchor is threaded with suture and the conical end is self-introduced into the bone soft tissue attachment site with a reusable introduction device. The suture ends are pulled to engage cancellous bone and to toggle and lock the anchor in bony tissue. A curved needle attached to the suture end(s) is used to secure soft tissue to bone.

Intended Use: The Multitak™ conical tip soft tissue suture anchors are intended for use as load bearing or non-load bearing suture anchors in the attachment of soft tissue to bone in various orthopedic surgical procedures. The anchors are self-introduced into bone or soft tissue and are available for use with suture size up to USP Size No. 2. The anchors are provided sterile and are intended for single use.

The Multitak™ conical tip soft tissue suture anchors are indicated for use in the following orthopedic soft tissue to bone fixation applications:

Shoulder:
- Bankart lesion repairs
- Acromio-clavicular repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

2600 S. Raney St.
Effingham, Il 62401

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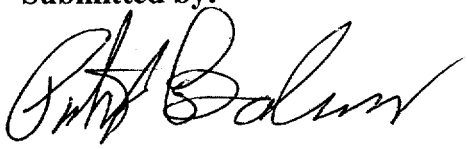
Elbow:	Ulnar or radial collateral ligament reconstruction
Knee:	Extra-capsular repairs Medial collateral ligament repair Lateral collateral ligament repair Posterior oblique ligament repair Illiotibial band tenodesis Patellar tendon repair VMO advancement Joint capsule closure
Foot/Ankle:	Medial/Lateral repairs/reconstructions Achilles tendon repairs

Predicate Device(s): The Multitak™ conical tip soft tissue suture anchors are similar in intended use, design, and materials to current commercially available suture anchors including the Multitak SS titanium suture anchors and the Biomet, Inc., Harpoon Suture Anchors.

Predicate Comparison: Performance testing comparing the pullout strengths and failure modes of the Multitak™ conical tip soft tissue suture anchors to Multitak SS titanium suture anchors demonstrated that the anchors are statistically equivalent.

Submitted by:



Patrick Balsmann
Manager, QA & Regulatory/Clinical Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

Mr. Patrick G. Balsmann
Director, QA & Regulatory/Clinical Affairs
Bonutti Research, Inc.
P.O. Box 1367
Effingham, Illinois 62401

Re: K010479
Device Name: Multitak™ Conical Tip Soft Tissue Suture Anchor
Regulation Number: 888.3040
Regulatory Class: II
Product Code: HTY and MBI
Dated: February 19, 2001
Received: February 20, 2001

Dear Mr. Balsmann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

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INDICATIONS FOR USE

Device Name: Multitak™ conical tip soft tissue suture anchor.

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K01 0479

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